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IN THE NAME OF

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FOR

METHOD AND APPARATUS FOR ADMINISTERING A VACCINE OR OTHER PHARMACEUTICAL

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TITLE OF THE INVENTION

METHOD AND APPARATUS FOR ADMINISTERING A VACCINE OR OTHER PHARMACEUTICAL

FIELD OF THE INVENTION

This invention relates to the administration of vaccines and other pharmaceuticals, and, in particular embodiments, to vaccines and other pharmaceuticals that are administered into or below the layers of the skin.

BACKGROUND OF THE INVENTION

The ability to properly administer vaccines and other pharmaceuticals is a critical component of modern healthcare. Children commonly receive an array of vaccinations, beginning at birth and continuing through adolescence. These inoculations generally include Hepatitis B ("Hep-B"), Diphtheria/Tetanus/Pertussis ("DTP"), *Haemophilus influenzae* type b ("Hib"), Polio ("IPV"), Pneumococcal conjugate ("PCV7"), Measles/Mumps/Rubella ("MMR") and Varicella (or "Chickenpox"). Vaccinations for Hepatitis A ("Hep-A"), Influenza, Lyme Disease and/or Pneumococcal Polysaccharide may also be administered in particular instances. Moreover, because some vaccines have only a limited period of efficacy, they must be administered to individuals on a periodic basis to ensure resistance to infection; with certain vaccines, so-called "booster shots" are required. By way of example, the influenza vaccine, or "flu shot," is routinely administered to adults on an annual basis at the beginning of the flu season in autumn. "Booster" Tetanus shots are recommended every ten years following the primary series of vaccinations that are administered during infancy, and upon an as-needed basis in response to cuts or puncture wounds in certain circumstances.

Most vaccines are administered by conventional needle injection. The depth of injection and corresponding configuration of the needle or needles required is different for various vaccines, yet the devices utilized (*e.g.*, syringes, and in some instances, needle-less injectors) are relatively simple and may be easily operated by healthcare professionals. However, there are a host of vaccines and other pharmaceuticals (including many currently in the development pipeline at pharmaceutical companies around the world) whose conventional means of

administration is significantly more complex, requiring skill, dexterity and careful attention to detail. By way of example, the Vaccinia (*i.e.*, "Smallpox") vaccine is among the vaccines in this category.

The Smallpox vaccine is generally administered into the skin over the insertion of the deltoid muscle or the posterior aspect of the arm over the triceps muscle. A multiple-puncture technique uses a pre-sterilized, bifurcated needle (such as those commercially available from Becton, Dickinson and Company; Franklin Lakes, NJ) that is inserted vertically into a vaccine vial, causing a droplet of vaccine to adhere between the prongs of the needle. The droplet contains the recommended dosage of vaccine, and its presence within the prongs of the bifurcated needle is confirmed visually. Holding the bifurcated needle perpendicular to the skin, approximately fifteen punctures are rapidly made with strokes vigorous enough to allow a trace of blood to appear after 15-20 seconds. These punctures are made in an area no larger than 5mm in diameter. Any vaccine remaining on the skin is wiped off with dry sterile gauze, and the gauze is disposed of in a biohazard waste container.

Some vaccines have never been administered to a large population, generally because they are still in an experimental phase (*e.g.*, an HIV/AIDS vaccine). Others have not been administered for many years. For example, the Smallpox vaccine described above was last administered on a large-scale basis in the late 1970's. The disease was officially declared eradicated by the World Health Organization on May 8, 1980, and vaccination programs were terminated. Now, more than twenty years later, a significant portion of the world population has not been immunized, and may rapidly fall victim to a mass epidemic should an outbreak occur. Moreover, diseases such as Smallpox tend to spread quickly. Some of these diseases do not require skin-to-skin contact for infection. They can be airborne or be transmitted by other pathological means, such as by nosocomial transmission (*i.e.*, the spread of a disease through a health care setting, such as a clinic or hospital, as is often the case with Ebola hemorrhagic fever ("Ebola HF") in African health care facilities).

Particularly during a time when the potential for outbreak of infectious disease is high, there is a need in the art for a simple medical device to administer vaccines and other pharmaceuticals, such as the Smallpox vaccine, an AIDS/HIV vaccine or any number of other products. Such a device would provide healthcare professionals with an important tool to use in administering vaccinations and inoculations in a fast, safe and simple manner. Moreover, since

non-healthcare professionals may also bear responsibility for vaccinating a population of individuals in an emergency situation, the need for a device that accomplishes these goals is now imperative.

SUMMARY OF THE DISCLOSURE

In one embodiment of the present invention, a vaccine/pharmaceutical administration device includes a group of lancets encased in a housing. The group of lancets may be affixed to a lancet base that is biased between two springs: an injection spring and a safety spring. The injection spring provides the necessary force to drive the group of lancets out of the injection end of the device and into or through the skin of a vaccination recipient, while the safety spring subsequently recoils the group of lancets back into the housing following vaccine/pharmaceutical administration. Thus, during operation, the group of lancets is exposed from the interior of the device housing only during the vaccination or inoculation. However, in alternate embodiments of the invention, the group of lancets may be exposed from the interior of the housing to deposit a vaccine or other pharmaceutical on the sharp tips of the lancets. The device may be actuated by a pushbutton trigger that fractures a set of shear pins in mechanical communication with the lancet base. Non-slip finger rests may additionally be included on the housing to enhance stability and for further ease of use.

In another embodiment, the vaccination device may be prepackaged with a vaccine or other pharmaceutical, or a component of the final pharmacological product that incorporates a vaccine or pharmaceutical. Different vaccine and pharmaceutical packaging arrangements may be used in connection with various embodiments of the invention to achieve, for example, optimal drug storage conditions and to enable the use of a range of vaccine and other pharmaceutical formulations (*e.g.*, multiple-component products, viscous formulations, etc.).

In a further embodiment of the present invention, a method of administering an injection or vaccine inoculation includes selecting an administration site, and deploying an injection with the aforementioned device. Prior to administering the vaccine or pharmaceutical product, a cap may be removed from the injection end of the device. The device may thereafter be actuated with the pushbutton trigger.

In a still further embodiment of the present invention, a method for manufacturing the aforementioned device includes an assembly process, which, in particular embodiments may

include an inline manufacturing procedure. The housing is provided, and the safety spring, lancet base, injection spring and pushbutton trigger are placed into the housing. Shear pins may be included to mechanically stabilize the lancet base. A finger support may be secured to the housing; in various embodiments, by a rotational locking mechanism. Securing the finger support may compress the injection spring such that an application of force to the pushbutton trigger that breaks the shear pins releases the tension in the injection spring to drive the lancets out of the injection end of the housing. The safety spring thereafter provides sufficient force to recoil the lancets back into the housing.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1a depicts a cross-sectional view of an injection device in accordance with an embodiment of the present invention. Figure 1b depicts an elevational view of the injection device from the actuation end thereof, and Figure 1c depicts an elevational view of the same injection device from the injection end thereof.

Figure 2 depicts a partial cross-sectional view of an injection end of an injection device with a cap in accordance with an embodiment of the present invention. A soft matrix material is illustratively included between the cap and the group of lancets included in the device.

Figure 3 depicts a cross-sectional view of a finger support with two finger rests in accordance with an embodiment of the present invention. The finger support illustratively depicted therein includes a locking channel.

Figure 4a depicts a cross-sectional view of a housing in accordance with an embodiment of the present invention. The housing illustratively includes a series of grooves therein, as well as a locking tab. Figures 4b and 4c depict elevational views of the housing from the injection end and actuation end thereof, respectively.

Figure 5a depicts an elevational view of a lancet base in accordance with an embodiment of the present invention. The lancet base illustratively includes a group of lancets. It further illustratively includes a series of guides configured about its axial circumference. Figures 5b and 5c depict elevational views of the lancet base from the injection end and actuation end thereof, respectively.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is based on a device that may be used to administer a vaccine or another pharmaceutical or injectate. It is particularly well suited for use with mammals in the treatment and prevention of human disease or in veterinary applications. The device may be particularly advantageous for the administration of vaccines and other pharmaceutical products that are delivered through the superficial epidermis; although, in alternate embodiments, the device may be used for the administration of vaccines and other pharmaceutical products at a variant delivery depth, such as intradermally, subdermally, subcutaneously or intramuscularly.

By way of example, Smallpox vaccine may be administered with the apparatus and methods of the present invention. Further, as it is believed that Smallpox vaccine may be effective in the treatment or prevention of diseases other than Smallpox (*e.g.*, Monkeypox), references herein to "Smallpox vaccine" or "Smallpox vaccination" shall be understood as being applicable to the treatment and prevention of these other disease conditions, as well. However, Smallpox vaccine is merely one example of a product that is suitable for use in connection with the device and methods of the present invention.

Numerous other products may be used in alternate embodiments, including, but in no way limited to, HIV/AIDS vaccines, Hep-B vaccines, DTP vaccines, Hib vaccines, IPV vaccines, PCV7, MMR vaccines and Chickenpox vaccines. Vaccinations for Hep-A, Influenza, Lyme Disease and Tetanus (both the primary vaccination series and booster shots), as well as Pneumococcal Polysaccharide are still further examples of vaccines and other products that may be administered with various embodiments of the invention.

The device and methods of the present invention are uniquely well suited to the mass vaccination of a population in the event of an epidemic or biological warfare. Thus, by way of example, the Anthrax vaccine may be administered with the device and methods of the present invention. Anthrax vaccine is conventionally administered in a series of three primary, subcutaneous injections at 0, 2 and 4 weeks, and three booster vaccinations at 6, 12 and 18 months; the vaccine manufacturer (BioPort Corporation; Lansing, MI) recommends annual booster shots after the primary series and initial set of booster vaccinations. Intramuscular versions of this vaccine are presently being studied, which may also be suitable for use with the device of the present invention, as well as other formulations that may be developed for variant delivery depths. Additionally, an outbreak of tularemia may be addressed with the device and

methods of the present invention. Tularemia may be spread through the bite of an infected insect or other arthropod (usually a tick or deerfly), by handling infected animal carcasses, by eating or drinking contaminated food or water, or by inhaling the bacterium *Francisella tularensis*. While no vaccine is presently available in the United States for tularemia, one is currently under review by the U.S. Food and Drug Administration. Other diseases commonly spread through bacterial infection, such as bacterial meningitis and Ebola HF, are still further examples of applications for the present invention. A vaccine for Ebola HF has yet to be developed, but the disease still represents a good example of the type of medical condition that may benefit from the device of the present invention; particularly, because the individuals responsible for performing a mass inoculation once a vaccine is developed are not likely to all be trained physicians.

In sum, as will be readily appreciated by one of skill in the art, there are a host of diseases and pathological conditions that may be addressed with the device and methods of the present invention, whether those diseases and conditions relate to a mass epidemic, to biological terrorism or by the more mundane transmission of illness in a human or animal population, and whether the vaccines and pharmaceutical products are presently available, under development or yet to be identified. In fact, the device and methods of the present invention may be used in connection with still further applications, such as veterinary practice (*e.g.*, to vaccinate cattle).

As illustratively depicted in Fig. 1, the device **100** includes a housing **101** with an injection end and an actuation end. The injection end may include an opening **111** through which a group of lancets **103** is exposed during the administration of a vaccination or injection of a pharmaceutical product. The group of lancets **103** may include any number of lancets (even just a single lancet), depending upon the particular delivery parameters of the vaccine or other pharmaceutical product being injected with the device **100**. Further, the actuation end of the device **100** may include a pushbutton trigger **106** that a user may operate to actuate the device **100**. The pushbutton trigger **106** may include a non-slip surface **117**.

The housing **101** may also include finger rests **107** for ease of device operation. The finger rests **107** may be disposed upon a finger support **118** that is attached to the device housing **101**. These finger rests **107** may include non-slip surfaces **116**, and may impart device stability by providing a grip that readily conforms to the fingers of a user. They also provide a surface against which to squeeze in order for a user to create the force required against the pushbutton

trigger **106** for device actuation. In the embodiment depicted in Figs. 1 and 3, there are two such finger rests **107** disposed at 180° opposite one another along the exterior, axial length of the housing **101**. Other configurations of finger rests **107** may be included in the device **100**, as well.

The housing **101** may be configured to any suitable size and scale, depending on a variety of factors, such as, but in no way limited to, the delivery parameters of the vaccine or pharmaceutical product, manufacturing requirements for the device and the ease of operation and manual handling by a user. In embodiments of the device **100** configured for the administration of a Smallpox vaccine, the housing **101** may be less than about five inches in overall length; more preferably, less than about two inches in overall length. It will be readily understood, however, that housings of alternate lengths (for Smallpox vaccine or otherwise) remain within the ambit of the present invention, and may even be more desirable than the relatively short housing length described above in particular instances (*e.g.*, to accommodate different gripping techniques employed by device users or to configure the devices for particular storage and shipping parameters).

The device **100** may further include a group of lancets **103**, each having a sharp tip. The group of lancets **103** may be affixed to a lancet base **104** that is free to move axially within the device housing **101**. In an embodiment of the present invention for the administration of Smallpox vaccine, there may be from about thirty to about forty lancets included in the group of lancets **103**, although a variant number of lancets may be included in particular instances (*e.g.*, to properly deliver a more or less concentrated version of a Smallpox vaccine that requires greater or fewer skin punctures, respectively, and to accommodate the particular delivery parameters of the wide variety of products that may be administered with the device **100**). For example, in various embodiments of the invention, the group of lancets **103** may include one lancet, five lancets, ten lancets, twenty lancets or any number of lancets therebetween or greater. Any configuration of the group of lancets **103** in the lancet base **104** may be utilized. In one embodiment, the individual lancets are arranged approximately equidistant from one another throughout the surface area of the lancet base **104** nearest the injection end of the housing **101**. Alternatively, the individual lancets may be arranged in a symmetrical pattern throughout the surface area of the lancet base **104** nearest the injection end of the housing **101**. Other lancet arrangements may be used, as well. In one embodiment of the device **100** that is particularly

well suited to administration of a Smallpox vaccine, there are approximately 36 lancets grouped approximately uniformly in the lancet base **104**.

The lancet base **104** may additionally include guides **113** configured about its axial circumference. In one embodiment, these guides **113** communicate with corresponding grooves **112** in the interior surface of the housing **101**. However, in alternate embodiments, no such grooves **112** are included in the housing **101**. The guides **113** (whether or not corresponding grooves **112** are included) may provide axial stability during device use, while reducing the frictional force imparted by the internal axial surface of the housing **101** as the lancet base **104** slides through the housing **101**. The lancet base **104** illustratively depicted in Figs. 1 and 5 includes four guides **113** configured at 0°, 90°, 180° and 270° about the axis of the lancet base **104**. Alternate guide configurations may be employed, as well. Additionally, the lancet base **104** may be in direct mechanical communication with the pushbutton trigger **106**.

The lancet base **104** may be biased between two springs: an injection spring **102** and a safety spring **105**. The injection spring **102** provides the necessary force to drive the group of lancets **103** out of the opening **111** in the injection end of the device **100** and force the sharp tips into and/or through the skin of a recipient. The safety spring **105** subsequently recoils the group of lancets **103** back into the housing **101**. In this fashion, the group of lancets **103** is exposed from the interior of the housing **101** only during the administration of a vaccination or injection of another pharmaceutical product. In alternate embodiments, the device **100** may be configured such that the group of lancets **103** may be exposed from the interior of the housing **101** to deposit the vaccine on their sharp tips prior to device use. The injection spring **102** may be configured between the lancet base **104** and the pushbutton trigger **106**; a portion of the lancet base **104** may reside within the injection spring **102**. The safety spring **105** is configured between the lancet base **104** and the injection end of the housing **101**; the group of lancets **103** and a portion of the lancet base **104** may reside within the safety spring **105**.

The lancet base **104** may be held in position with respect to the device housing **101** prior to actuation by shear pins **108**. Any suitable number of shear pins **108** may be used in connection with various embodiments of the present invention, and they may be arranged in any desirable configuration, such as symmetrically about the longitudinal axis of the device **100**. In one embodiment, two shear pins **108** are included and are disposed 180° opposite one another. The shear pins **108** are each attached on one end to the lancet base **104**. On their opposing end,

each shear pin **108** is in contact with the device housing **101**. In one embodiment of the present invention, as depicted in Fig. 1, the ends of the shear pins **108** that contact the housing **101** rest against a ridge **113** (depicted in Fig. 4a) on the interior of the housing **101**. When the device **100** is fully assembled, the force of the compressed injection spring **102** against the lancet base **104** forces the end of the shear pins **108** in contact with the device housing **101** against the ridge **113**. Additionally, as depicted in Fig. 1, the lancet base **104** may be in direct mechanical contact with the pushbutton trigger **106**. This may provide still further support for the shear pins **108** against the ridge **113**. Upon application of sufficient force to the pushbutton trigger **106** the shear pins **108** fracture, thereby releasing the lancet base **104** such that it can move freely toward the injection end of the device **100**. The compressed injection spring **102** may then drive the group of lancets **103** out of the opening **111** to administer the injection or vaccination.

As illustratively depicted in Fig. 2, the device **100** may further include a cap **109**, both in those embodiments where the device **100** is prepackaged with a vaccine or other pharmaceutical product, and those embodiments where the device **100** is not prepackaged with a vaccine or other pharmaceutical product. In embodiments where the device **100** is prepackaged with a vaccine or other pharmaceutical product, the sharp tips of the group of lancets **103** may be maintained in a soft matrix **110** that protects the sharp tips and prevents the product from leaking through the opening **111** configured on the injection end of the device **100**. In embodiments where the device **100** is prepackaged with a viscous product (*e.g.*, a paste) the sharp tips of the group of lancets **103** may be maintained in a casing that includes a well for each of the sharp tips (not shown). The wells may protect the tips and prevent the viscous product from escaping through the opening **111** configured on the injection end of the device **100**. The cap **109** may be included around the soft matrix **110** or casing of wells (not shown), and may be removably attached to the injection end of the device housing **101**.

As noted above, the device **100** may be prepackaged with a vaccine or other pharmaceutical, or a component of the final pharmacological product that incorporates a vaccine or pharmaceutical. In the latter instance, where a multiple-component vaccine or pharmaceutical product is utilized, a first component may be prepackaged with the device **100**, while the second component may be maintained separately. The sharp tips of the group of lancets **103** including (*e.g.*, coated with) the first component may then be "dipped" into a container with the second component; thereby generating a two-component pharmacological mixture for administration

with the device **100**. The sharp tips of the group of lancets **103** may be exposed from the opening **111** at the injection end of the device **100** to accomplish the dipping operation, although that is not required.

The device **100** may further be configured for inline manufacturing. The housing **101** may be provided, and the safety spring **105**, lancet base **104** (with group of lancets **103** oriented toward the injection end of the housing **101**), injection spring **102** and pushbutton trigger **106** may then be placed into the housing **101** (in the embodiment of the present invention illustratively depicted in Fig. 1, these components may be placed into the housing **101** in the aforementioned order). Shear pins **108** may be included to mechanically stabilize the lancet base **104**, and may rest against a ridge **113** in the interior of the housing **101**. A finger support **118** may then be secured to the housing **101**; in various embodiments, by a rotational locking mechanism.

As illustratively depicted in Figs. 3 and 4a, the rotational locking mechanism may include a locking tab **115** disposed on the interior of the housing **101** that communicates with a locking channel **114** configured on the interior of the finger support **118**. The locking tab **115** may first slide through the locking channel **114** when the finger support **118** is placed on the actuation end of the housing **101**. Once the finger support **118** is moved a predetermined length along the longitudinal axis of the housing **101**, it may be rotated such that the locking tab **115** secures the finger support **118** to the housing. Securing the finger support **118** to the housing **101** may also compress the injection spring **102** between the pushbutton trigger **106** and lancet base **104**, but not to such a great degree that the shear pins **108** break. This act of securing may also place the lancet base **104** and pushbutton trigger **106** in direct mechanical contact in such fashion as to support the shear pins **108** against the ridge **113**. Any number of rotational locking mechanisms may be included in the device **100**. In one embodiment, two such mechanisms are included (*i.e.*, a pair of locking tabs **115** and locking channels **114** disposed 180° opposite one another. A cap **109** may be secured to the housing **101** at any point in the manufacturing operation (*e.g.*, before placing the various components into the housing **101**, after securing the rotational locking mechanism or at any other suitable point in the manufacturing operation). The cap **109** may protect the group of lancets **103** and/or coat the sharp tips of the group of lancets **103** with a vaccine or other pharmaceutical product.

EXAMPLE

Administration of a Vaccination

A device of the present invention is configured for inoculation with a Smallpox vaccine. An end cap is removed from the device and an appropriate vaccine administration site is selected (*e.g.*, the skin over the insertion of the deltoid muscle or the posterior aspect of the arm over the triceps muscle). A group of 36 lancets is included in the device, and are pre-coated with a Smallpox vaccine. The injection end of the device is held against the surface of the skin at the vaccine administration site. The device is actuated by depressing a pushbutton trigger configured thereupon. Upon actuation, the group of 36 lancets coated with the Smallpox vaccine is exposed from an opening at the injection end of the device housing. These lancets pierce the skin of the recipient, thereby depositing the Smallpox vaccine into the recipient's superficial epidermis. The group of lancets is subsequently recoiled into the housing of the device by operation of a safety spring included therein. The device is then disposed of, and the vaccination is complete. Any excess vaccine remaining on the skin surface may be wiped off with sterile gauze.

While the description above refers to particular embodiments of the present invention, it should be readily apparent to people of ordinary skill in the art that a number of modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true spirit and scope of the invention. The presently disclosed embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than the foregoing description. All changes that come within the meaning of and range of equivalency of the claims are intended to be embraced therein.